ABLE
LABORATORIES
INC. Subsidiary of DynaGen, Inc.

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June 12, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm 1061
Rockville, MD 20852
Docket Number: [57 FR 17990, Apr. 28, 1992; 57 FR 29353, July 1, 1992]

CITIZEN PETITION

The undersigned submits this petition under 21 CFR 314.122 of the Federal Food, Drug and Cosmetic Act, or any other applicable statutory provision, for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.10, to request the Commissioner of Food and Drugs to determine if the drug product ROWASA® Suppositories, 500 mg manufactured by Solvay Pharmaceuticals, Inc. (approved by the FDA in 1990 - NDA # 19919) was withdrawn from sale for safety or efficacy reasons. ROWASA Suppositories are indicated for the treatment of mild to moderate distal ulcerative colitis, proctosigmoiditis or proctitis.

Action Requested

Able Laboratories Inc. respectfully requests the FDA to determine whether the product ROWASA® rectal suppository, 500 mg was withdrawn from the market due to safety or efficacy reasons.

OOP-1340 [redacted]

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6 Hollywood Court ◢ South Plainfield ◢ New Jersey 07080
Telephone: 908-754-2253 ◢ Fax: 908-754-2476

Statement of Grounds

Able Laboratories, Inc. would like to pursue an approval to market the generic version of the drug product ROWASA® suppositories, 500 mg. Since the brand reference drug product has been discontinued, it would be important to know whether this product had issues of safety and/or effectiveness, and whether these issues resulted in its withdrawal from the market. We are aware of the dissolution failures that precipitated the recall of ROWASA® in the fall of 1999, however, before we pursue additional development activities with the above referenced product we must have a thorough understanding of any and all of the underlying issues pertaining to the withdrawal. The outcome of this determination will assist Able Laboratories in discussing with the FDA, the design of the study(s) required to be performed by Able Laboratories in support of a submission for the marketing approval of a generic version of the product or a 505(b)2 submission with pre-existing data on safety and efficacy.

> In a response to a request for determination of bio-equivalence requirements for a study comparing ROWASA® suppositories and Able's potential product, Dr. Gary Buehler, Acting Director of the Office of Generic Drugs at the Center for Drug Evaluation and Research suggested in a letter to Mrs. Iva Klemick, Director of Regulatory Affairs at Able Laboratories, that a Citizen Petition requesting investigation into the reason(s) for the discontinuation of ROWASA suppositories be submitted to the FDA.

As required per 21 CFR 314.122, attached in Appendix 1 is the available evidence for discontinuation of ROWASA® suppositories (which only mention dissolution and/or stability issues as reasons for the recall).

Environmental Impact

Able Laboratories claims categorical exclusion of any environmental impact under 21 CFR 25.24.

Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Signature: _____

Mr. Shashikant Shah R.Ph.
V.P. Quality and Regulatory Affairs

Name of petitioner: ABLE Laboratories, Inc.

Mailing address: 6 Hollywood Court CN1013
South Plainfield, New Jersey 07080

Telephone number: 908.754.2253 Extension 505

APPENDIX 1

ABLE LABORATORIES INC. Subsidiary of DynaGen, Inc.

Inflammatory Bowel Disease Suppository Recalled

NEW YORK, Jun 23 (Reuters Health) -- An anti-inflammatory rectal suppository known as mesalamine (Rowasa) is being recalled and the company has halted production of the drug, the manufacturer, Solvay Pharmaceuticals, confirmed on Tuesday.

Rowasa suppositories are approved by the Food and Drug Administration for the treatment of active ulcerative proctitis, which is an inflammation of the rectum and anus. Doctors also prescribe the drug for Crohn's disease and ulcerative colitis, both inflammatory disorders of the digestive tract.

According to Solvay, approximately 100,000 patients took Rowasa suppositories in 1998.

The recall began at the wholesale level on May 18, after the company was informed by a patient that the drug failed to fully dissolve. The company conducted tests and determined that there was a widespread problem with the dissolving of the drug, which resulted in the recall, a Solvay spokeswoman told Reuters Health.

The company had recalled a small number of lots of the drug in December for the same reason.

However, the company has yet to find the reason for the problem, the spokeswoman said. She noted that Solvay is committed to the long-term production of the drug, but the company does not know when production will resume. She said that it could be a matter of days or months.

The spokeswoman noted that Rowasa is available in an enema form and is still on the market, but the drug preparations do not work exactly in the same way. The company has suggested that patients contact their physicians regarding alternative therapies, such as steroids, that help fight inflammation.

http://www.allhealth.com/conditions/digestive/news/0%2C4800%2C135_127161%2C00.html